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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/498,305	02/04/2000	Burt D. Ensley	2001605-0007	8631

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EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

14

DATE MAILED: 08/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/498,305

Applicant(s)

ENSLEY, BURT D.

Examiner

William W. Moore

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2002 and 01 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,9-14 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 9-14 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1652

DETAILED ACTION

Continued Prosecution Application

The request filed on July 1, 2002, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/498,305 is acceptable and a
5 CPA has been established. An action on the CPA follows.

Response to Amendment

Applicant's Amendment B, Paper No. 10 filed October 19, 2001, has been entered. Claims 3 and 15 were canceled at Applicant's request and their cancellation, together with the amendment to claim 1 submitted with Paper No. 10, overcome the rejections of
10 record of claims 1, 5 and 9-13 herein for lack of enablement. Claims 1, 2 5, 9-14 and 17 remaining in the application are examined herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

15 A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20 The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30 Claims 1, 2, 5, 11-14 and 17 remain rejected for reasons of record under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Weiss, WO 98/06830, of record, or rejected for reasons of record under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) his corresponding U.S. Patent 6,277,622, having a common disclosure, made of record herewith.

Applicant's arguments filed October 19, 2001, have been fully considered but they are not persuasive. While the relevant portions of the U.S. Patent to Weiss corresponding

Art Unit: 1652

to the identical disclosure of the PCT publication of Weiss, previously cited, are discussed in this statement, this is essentially the rejection of record. At page 3 of Paper No. 10 Applicant suggests that a "careful read[ing] of the[se] sections [of Weiss ('830) cited in Paper No. 9 mailed January 2, 2002] reveals that they cannot anticipate or render

5 obvious" an invention claimed herein because "the present claims recite methods and kits in which lysyl oxidase and not-previously-crosslinked tropoelastin are maintained separate from one another until they are applied to a wound." This is unpersuasive because the amended claim 1 herein describes "a method . . . comprising . . . providing isolated tropoelastin . . . and isolated lysyl oxidase . . . separated from each other; and applying

10 both said tropoelastin and said lysyl oxidase simultaneously" and because Weiss discloses, at col. 13, lines 51-56, that "an expression product of the invention", lysyl oxidase, "may be included in a matrix including [a] . . . tropoelastin . . . based . . . containing matrix which is . . . applied to the wound." Weiss thus indicates that the enzyme and its non-crosslinked substrate are simultaneously applied to a wound where the tropoelastin is within

15 a matrix, and that the enzyme is separate from the matrix prior to addition thereto where such addition of the enzyme would be superfluous if the tropoelastin were already cross-linked. The preamble of claim 1 does not exclude application of tropoelastin together with matrices in reciting, "a method comprising", and does not exclude the application of other materials in addition to lysyl oxidase and tropoelastin in the practice of the method, thus

20 Weiss anticipates the method described by the amended claim 1. Weiss further teaches, col. 13, lines 57-59, that the enzyme "can be formulated in suitable carriers, buffers and other conventional delivery systems", anticipating methods of claims 11-14 and 17. Weiss also discloses, see col. 6, lines 52-61, that there are a variety of mammalian and avian lysyl oxidases, and that the preferred lysyl oxidase for application to a person is the

Art Unit: 1652

human enzyme, anticipating claim 2. In addition, Weiss contemplates, col. 13, lines 33-35, the use of the enzyme with a variety of forms of tropoelastin, anticipating claim 5.

In the alternative, the disclosure of Weiss is considered to have rendered the subject matters of claims 1, 2, 5, 11-14 and 17 obvious to one of ordinary skill in the art at the time the invention was made because such an artisan at that time would have reasonably considered the disclosure of Weiss to teach that simultaneous administration of both the enzyme and its tropoelastin substrate, and a variety of forms, thereof, to a wound would promote healing and that the enzyme and substrate should be separated from one another so the process of cross-linking would commence with the application to the wound. Such an artisan would have considered the further teachings of Weiss to indicate the application of species-mapped tropoelastin and the use of mixtures of carriers and kits of claims 12-14 and the application device of claim 11 herein. The rejection of record is sustained as to claims 1, 2, 5, 11-14 and 17.

Claim 9 is rejected under 35 U.S.C. §103(a) as obvious over Weiss, U.S. Patent 6,277,622, as applied to claims 1, 2, 5, 11-14 and 17 above, and further in view of Kagan, in Regulation of Matrix Accumulation, pp. 321-398, 1986, of record.

The teachings of Weiss et al., discussed above, are taken as before. Kagan teaches, pp. 380-385, that fluctuations in components of the diet can influence native lysyl oxidase activity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to repeatedly apply lysyl oxidase, and its copper ion cofactor not excluded by the method of claim 1, after a simultaneous application of lysyl oxidase and tropoelastin, where both were previously kept separate, as taught by Weiss, because such an artisan would have readily recognized that the enzyme applied at any particular time to the wound, including the initial application, may suffer a loss of activity at the wound site where a decrease in the levels of copper ion in the body, hence at the site of the wound, or an increase in levels of ascorbic acid in the body, hence at the site of the wound, would reduce the activity of the previously applied enzyme, requiring its replenishment.

Art Unit: 1652

Claim 10 is rejected under 35 U.S.C. §103(a) as obvious over Weiss, U.S. Patent 6,277,622, as applied to claims 1, 2, 5, 11-14 and 17 above, and further in view of Khadem et al., U.S. Patent No. 5,552, 452, of record.

The teachings of Weiss et al., discussed above, are taken as before. Khadem et al. teaches the use of tissue glue to approximate separated wound tissues as well as application of healing molecules. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sutures, staples, adhesive strips, or tissue glue, the latter taught by Khadem et al., to approximate separated wound tissues with mechanical means according to Khadem et al. and apply lysyl oxidase and tropoelastin simultaneously, where both were previously kept separate, as taught by Weiss, because such an artisan would have readily recognized that approximation of wound tissue during the application of healing molecules would reduce the formation of scar tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 7:00AM-5:30PM EST on Mondays and Wednesdays, between 7:00AM-1:30PM EST on Tuesdays and Thursdays, and between 8:30AM and 5:00PM EST on Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
August 5, 2002



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